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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,237	11/26/2001	Lasse Wesseltoft Mogensen	8465/20	1444

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EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,237

Applicant(s)

MOGENSEN ET AL.

Examiner

Cris L. Rodriguez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16, 18-22 and 24-30 is/are rejected.
- 7) ☒ Claim(s) 13-15 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species b) figures 6-12, claims 1-16, and 18-30 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that there is a misunderstanding of the figures and based on the presence of generic claims, since all the figures relate to an injector device for placing a subcutaneous infusion set. This is not found persuasive because applicant's disclosure has set forth that the figures are different embodiments establishing that they are distinct and mutually exclusive. The fact that some claims might be generic does not mean that the claims cannot be restricted to a single species. MPEP 806.04(e) and (f).

The requirement is still deemed proper and is therefore made FINAL.

2. Please note that claim 29 has been included in the examination upon allowance of generic claim 25.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the needle and the cannula as separate elements, since the injection device and the infusion set 14 are different devices as described in the specification. The current drawings show only one needle/cannula with two different references numerals. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

what
about fig 1-5
→

Art Unit: 3763

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "113" has been used to designate both infusion tubing set and spring (see Figs. 6-8). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to because

- Elements "113" and "136" are confusing in the drawings because it is not clear and consistent if they are a spring or a strip as shown in figures 6-8, and 12;
- None of the drawings for figures 6-11 show where is the transversal cut shown in figure 12.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 10, 19, 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 24, there is no antecedent basis for "the strips".
- Claim 25, there is no antecedent basis for "the drive".
- Claims 10 and 19, there is no antecedent basis for "the plunger head".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-12, 16, and 18-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Safabash et al (US 6, 293,925).

Safabash discloses an insertion device 10,110 (figs. 1-29), having a housing 28,128, a plunger 30,130 having substantially non-detachable secured thereto an insertion needle in hub 18, a drive 38,138 or 54,154. The plunger head includes a safety retainer 202. Figures 40a-40d show a cover for covering the infusion set and another cover to cover the insertion needle.

Allowable Subject Matter

10. Claims 13-15, and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claim 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Claims 25-30 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Art Unit: 3763

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Van Antwerp et al., Bartholomew et al., Konopka et al., Koenig et al., Larsen et al., Funderburk et al., Nielsen et al., and Chanut.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

June 4, 2003



Cris L. Rodriguez
Examiner
Art Unit 3763

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700